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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/527,440	03/17/2000	Hiroki Nakae	HIRA.0003	3095

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EXAMINER

ZEMAN, MARY K

ART UNIT

PAPER NUMBER

1631

15

DATE MAILED: 12/11/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/527,440

Applicant(s)

NAKAE ET AL.

Examiner

Mary Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-8,11,19,20,22,24,28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-8,11,19,20,22,24,28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

The amendment filed 11/19/01 has been entered and considered. Claims 5, 21, 23, 25, 26 and 27 have been canceled. Claims 1-4, 6-8, 11, 19, 20, 22, 24, 28 and 29 are pending in this application and are examined herein.

Claim Objections

Claim 1 is objected to because of the following informalities: in claim 1, line 8, the word "dentified" is apparently a typographical error, and the proper word appears to be "identified". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8, 11 and 24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A thorough review of the above rejected claims according to the guidelines for computer related inventions set forth in MPEP 2106 results in the conclusion that these claims are drawn to non-statutory subject matter, as they merely manipulate data. To be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan (discussed in i) below), or (B) be limited to a practical application within the technological arts (discussed in ii) below). See *Diamond v. Diehr*, 450 U.S. at 183- 84, 209 USPQ at 6 (quoting *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1877)).

Claim Rejections - 35 USC § 112

Claims 6, 24, 28 and 29 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 sets forth that the system further comprises a second database. The system of claim 1 does not comprise a database, such that this limitation makes sense. The system of claim 1 comprises a *means for accessing* a database.

In claim 24, and claim 28, the metes and bounds of the phrase “means for positioning exons associated with genetic functions of interest on the plurality of different DNA nucleotide sequences” are entirely unclear. An exon is a region of a polynucleotide or genomic sequence that encodes a part of a protein. The exon itself has no “genetic function” nor is it physically “positioned” “on a nucleotide sequence.” The characteristics of an exon can be tentatively identified in a genomic sequence, and that information can be associated with a region of the sequence in a database- but this is not what the claim sets forth. *Applicant has not provided specific arguments regarding this rejection.* The response summarizes various points of the invention, and indicates that a variety of off the shelf programs *could be utilized* to carry out the intended functions of the claim, however, the claim does not recite these specific functions or programs, nor does the claim exactly what it is intended to accomplish.

Claim 29 recites improper Markush language referring to options (a)-(e), and the limitations do not make sense when compared to the system of claim 20. It is entirely unclear where this limitation should be placed in the system of claim 28. For example, is the exon predicting program part of the means of positioning? The means of collating? What is the intent of (c) and (d) “from at least one EST Database?” This does not make grammatical sense in claim 21, or in claim 20, nor does it clearly identify where in should be added to the system of claim 20. Further, the specification does not identify what “a SNP potential” is. Either a polynucleotide has a single nucleotide polymorphism, (SNP) or it does not. In theory, ANY single nucleotide of a polynucleotide in a database of polynucleotides has some *potential* for being polymorphic. Further, option (e) also makes no grammatical sense in context, and the limitation “having no known function” completely is at odds with the notion of “genetic functions of interest.” How can the system operate if it is supposed to position genetic functions

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of interest, or correlate genetic functions of interest when you don't know what the function is?!
The Examiner notes that this rejection applied to previously pending, *identically formed* claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4, 6-8, 11, 19, 20, 22, 24, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Vijg et al. (WO 98/06872).

The claims are drawn to systems for designing primers useful for PCR. The system comprises a variety of means to identify a plurality of potential primer sequences from DNA sequences extracted from a database of DNA sequences by using selection conditions of base length, T_m, GC content, etc. The system further comprises means to position the primer sequences against the original DNA sequence, select appropriate pairs of those sequences in order to be able to use the for PCR of exons in the DNA sequence, and collate all the resulting information. The system does not set forth that these means must all be interrelated or interconnected in any particular way. The claims drawn to the computer software product which mimic the above system also do not set forth any specific interrelatedness, or particular series of steps that must be performed in a certain order. These claims merely require that the means be available.

Vijg et al. (WO 98/06782) disclose systems, software, and methods for designing primers that comprise each of the recited means, and result in the selection and correlation of PCR primers with exons of DNA sequences that have been retrieved from a database. Figures 6-8 of Vijg et al. clearly identify the means and functions disclosed in the publication, and how those means and functions are used to identify, and design PCR primers. (see also pages 17-19, 23-28) Design parameters include base length, T_m, and GC content, as well as position in relationship to an exon, sequence similarity to other sequences, etc. Vijg et al. specifically note that primers for the amplification of multiple exons from a gene can be identified, designed and collated by the disclosed system. (page 5 line 22) Vijg et al. indicate that genes of varying known function can be analyzed (RB, p53). Therefore, Vijg et al. meets the limitations of the above rejected claims.

Claims 1-4, 6-8, 11, 19, 20, 22, 24, 28 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Vijg et al. (US Patent 6,007,231).

Vijg et al. (US Patent 6,007,231; an equivalent of the above WO patent) disclose systems, software, and methods for designing primers that comprise each of the recited means, and result in the selection and correlation of PCR primers with exons of DNA sequences that have been retrieved from a database. Figures 6-8 of Vijg et al. clearly identify the means and functions disclosed in the publication, and how those means and functions are used to identify, and design PCR primers. (see columns 11-14) Design parameters include base length, T_m, and GC content, as well as position in relationship to an exon, sequence similarity to other sequences, etc. Vijg et al. specifically note that primers for the amplification of multiple exons from a gene can be identified, designed and collated by the disclosed system. (col 3 lines 30-34) Vijg et al. indicate that genes of varying known function can be analyzed (RB, p53). Therefore, Vijg et al. meets the limitations of the above rejected claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Mary K Zeman** whose telephone number is (703) 305-7133. The examiner can generally be reached between the hours of 7:00 am and 1:00 pm Monday through Friday.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

Official fax numbers for this Art Unit are: (703) 308-4242, (703) 872-9306. An *unofficial* fax number, direct to the Examiner is (703) 746 5279. Please call prior to use of this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz
12/4/01


MARY K. ZEMAN
PATENT EXAMINER
